All Silicone Gastrostomy Balloon Catheter
(Standard Type)

Do not reuse

[WARNINGS]

< Usage >

[1] The position of the fixation plate should be set appropriately to avoid excessive compression of the gastric wall and abdominal wall during placement.
[Otherwise, tissue necrosis due to compression or catheter dislodgement due to balloon burst may occur.]

[2] When removing the catheter, if the catheter adheres to the fistula, do not pull it forcibly and remove it endoscopically.
[Fistula mucosal tissue or the catheter may be damaged.]

[3] Before administration of nutrients, etc., make sure that the catheter tip is appropriately placed in the stomach. Special attention should be paid to catheter dislodgement due to accidental removal.
[Serious complications such as peritonitis may occur due to intraperitoneal leakage of nutrients, etc.]

[CONTRAINDICATIONS, PROHIBITIONS]

[1] Do not reuse (use for one patient only).
[This product is for one-time use only. The quality and performance after use cannot be guaranteed. Furthermore, reuse may involve risk of contamination (infection) to the patient. Contamination of this product can result in patient injury, illness or death.]

[2] Reworking and re-sterilization are prohibited.
[Reworking of this product may cause product failure. This also may result in patient injury, illness or death.]

< Target Patients >

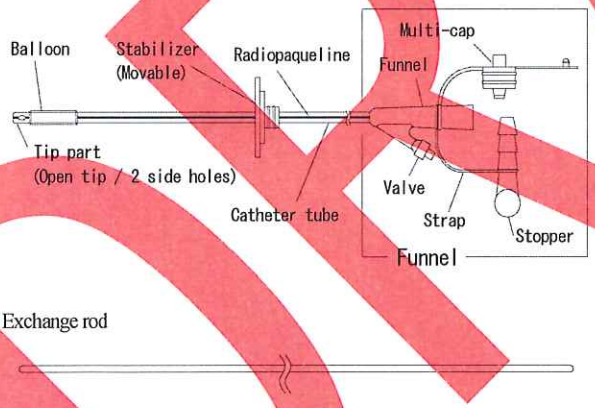
Do not use if a fistula has not been firmly formed or if the fistula is damaged or abnormal.
[If this product cannot be placed in the stomach, the nutrient, etc. may leak into the abdominal cavity and cause serious complications such as peritonitis.]

[SHAPE, STRUCTURE AND PRINCIPLE]

This product has been sterilized with ethylene oxide gas.

< Shape >

▪ All Silicone Gastrostomy Balloon Catheter (Standard Type)



▪ Exchange rod

▪ All Silicone Gastrostomy Balloon Catheter (Standard Type)

Size	Outer diameter	Valve color	Balloon capacity	Specifications
12Fr	4.0mm	White	5mL	Total length 225 mm Depth mark at 10 mm intervals between 20 mm and 100 mm from the balloon end Open tip, 2 side holes
14Fr	4.7mm	Green		
16Fr	5.3mm	Orange	10mL	
18Fr	6.0mm	Red		
20Fr	6.7mm	Yellow		
22Fr	7.3mm	Violet		
24Fr	8.0mm	Blue		

▪ Exchange rod:
All Silicone Gastrostomy Balloon Catheter (Standard Type)

Gastrostomy catheter for replacement size	Exchange rod outer diameter
12 to 14Fr	φ0.8mm
16 to 24Fr	φ1.4mm

< Raw Materials >

▪ Catheter: Silicone rubber, polypropylene, Styrene elastomer
▪ Exchange rod: Polypropylene

< Principle >

After inserting a catheter into the gastric fistula, expand the balloon to fix and place the catheter. Inject nutrients, etc. from the end port. Nutrients, etc. are administered into the stomach through the lumen. The use of the exchange rod in changing catheters reduces the risk of inadvertent insertion of the catheter into the abdominal cavity.

[INTENDED USE]

In patients who cannot orally take nutrition, this product is placed through a gastrostomy and used for administration of drugs such as nutrients, food and fluids for a short period of time. It can also be used for gastric decompression.

[EFFECT]

The nutritional supplement can be administered from the gastrocutaneous fistula through the catheter.

[PERFORMANCE]

▪ The sterility assurance level (SAL) of 10^{-6} can be guaranteed.
▪ Sterilization residues: Conform to ISO10993-7.
▪ Free of materials of biological origin and conforming to biological safety requirements.
▪ Being durable for 29-day continuous use
▪ Stability and durability are maintained for 5 years.
▪ Catheter tensile strength is not less than 15 N.

[OPERATING OR USING METHOD]

The followings are general instructions for use.

< Procedure for Catheter Replacement >

[1] Confirm that the fistula has been surely formed and has no abnormality (a state in which the usual fistula formation period of 3 weeks has completed after percutaneous endoscopic gastrostomy (PEG), and it has been confirmed that the gastric wall and abdominal wall do not dissociate).
[2] Apply lubricant agent to the inner lumen of the proximal side of the catheter placed in the fistula and insert the exchanging rod.
[3] Remove the catheter placed in the fistula according to its usage, taking care not to remove the exchange rod.
[4] Lubricate the fistula.
[5] Insert the catheter into the fistula from the tip side along the exchange rod, and place the balloon into the stomach.
[6] Inflate the balloon by injecting the specified volume of sterile distilled water through the valve.
[7] Gently pull up the catheter, confirm that the balloon touches the gastric wall lightly in the stomach, and remove the exchange rod.
[8] Move the fixation plate to the abdominal wall side. At this time, position it appropriately so that it does not contact the skin. (Give 1 - 2 cm space from the body surface.)
[9] Confirm that the catheter is securely inserted into the stomach under endoscopy or X-ray fluoroscopy.

< Procedure for Replacement Not Using Endoscope or X-Ray Fluoroscope as the First Choice to Check the Placement Site >

[1] Before removing the catheter already placed in the fistula, inject 20 - 30 mL of saline (it is better to stain the saline with red food coloring, etc.) into the stomach from the catheter.
[2] After replacing the catheter according to < **Procedure for Catheter Replacement** > [1] to [8] described above, draw up saline, which has been injected into the stomach in advance, via the catheter with a syringe to confirm that the catheter is securely inserted in the stomach.
[3] If the insertion into the stomach cannot be confirmed with this method, be sure to reconfirm it under endoscopy or X-ray fluoroscopy.

< Measures to Deal with Catheter Dropout, such as Accidental (Self) Removal >

[1] Confirm that there is no abnormality in the fistula, and apply lubricant to the fistula and exchange rod.
[2] Insert the exchange rod from the fistula.
[3] According to < **Procedure for Catheter Replacement** > [5] to [9] described above, place the catheter and confirm the successful insertion into the stomach.

- Fistula without any placement narrows in a short time. Therefore, appropriate measures should be taken to prevent the fistula narrowing, and a replacement catheter should be placed promptly.
- Excessive insertion may damage the fistula. If the fistula has already narrowed, discontinue the use and take appropriate measures.

< Combination Devices >

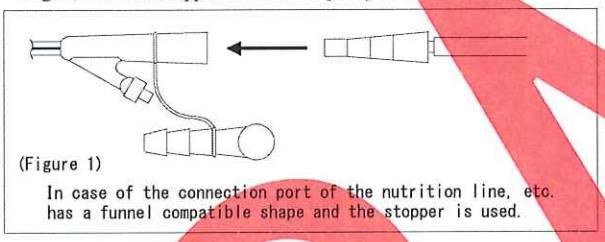
This product should be used in combination with the following devices.

Name	Specifications
Nutrition line	End part shape: Catheter tip or bamboo sprout shape
Syringe (for balloon inflation)	▪ Slip type ▪ Volume: 2 - 10 mL
Syringe (for flushing)	▪ Catheter tip type ▪ Volume: 5 - 10 mL
Syringe (to eliminate clogging)	▪ Catheter tip type ▪ Volume: Not less than 30 mL
Sterilized distilled water	-
Lukewarm water	-
Lubricant	Water-soluble lubricant
Nutrient	Enteral nutrient

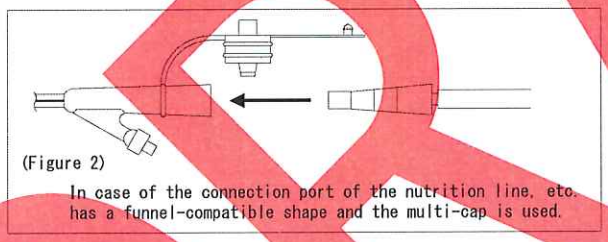
< Procedure for Connection to a Nutrition line >

Decide whether to use a multi-cap or stopper depending on the type of connecting port of the nutrition line, etc.

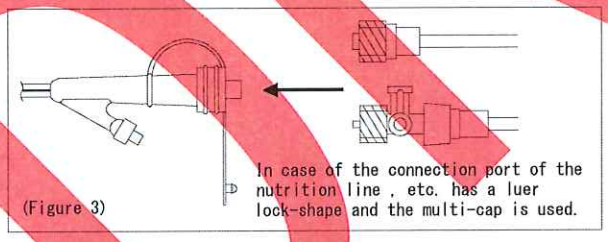
- When using the stopper (Figure 1)
  The stopper is used when the connection port of the nutrition line, etc. has a shape compatible with the funnel and the user wants to select an easier operation method.
  Remove the multi-cap if the stopper only is used.
- When using the multi-cap (Figure 2) (Figure 3)
  The multi-cap can be used both with the funnel-shaped and lure-shaped bags. Remove the stopper if the multi-cap only is used.



(Figure 1)
In case of the connection port of the nutrition line, etc. has a funnel compatible shape and the stopper is used.



(Figure 2)
In case of the connection port of the nutrition line, etc. has a funnel-compatible shape and the multi-cap is used.



(Figure 3)
In case of the connection port of the nutrition line , etc. has a luer lock-shape and the multi-cap is used.

< Procedure for Nutrient Administration >

[1] Immediately before administration of nutrients, etc., gently pull this product to make sure that there is no catheter dislodgement/abnormality.
[2] Flush with 5 - 10 mL of lukewarm water. ("Flushing" in this document refers to the operation in which an appropriate amount of lukewarm water is taken into a syringe and injected rapidly.)
[3] Connect the nutrition line, etc. to the funnel of this product.
[4] Inject nutrients, etc. Drugs should be dissolved in as much lukewarm water as possible before injection.
[5] After injection of nutrients, etc., be sure to flush the catheter lumen with at least 10 mL of lukewarm water.
[6] Attach a stopper or multi-cap to the catheter funnel.

< Procedure for the Decompression in the Stomach >

[1] Remove the catheter stopper or multi-cap from the funnel and decompress the stomach. In the case of gastric emptying, discharge the contents into a container, etc., then flush with 10 mL or more of lukewarm water from the catheter funnel to wash the catheter lumen.
[2] Attach a stopper or multi-cap to the catheter funnel.

< Procedure for Catheter Removal >

[1] Withdraw sterilized distilled water in the balloon with a syringe.
[2] Gently remove the catheter from the fistula.

< Precautions for Use Related to the Operating Procedures >

[1] When replacing gastrostomy catheters of other makers, do not use the exchange rod.
[Specifications may not be compatible with products of other companies.]
[2] Do not use any rod other than the supplied exchange rod.
[If an exchange rod unsuitable for the catheter size is selected, the exchange rod may not be inserted/removed.]
[3] Insertion/removal of the exchange rod should be performed while keeping the catheter straight.
[Manipulation of the exchange rod may be difficult.]
[4] Insertion/ removal of the exchange rod should be performed after removing the stopper and multi-cap.
[With the stopper and multi-cap attached, the exchange rod cannot pass through the catheter lumen.]
[5] Do not push the exchange rod too much.
[Excessive pushing of the exchange rod may cause damage (perforation, etc.), bleeding, etc.]
[6] Before using this product, make sure that the balloon inflates and deflates without fail.
[7] When inflating/deflating the balloon, pay attention to the following points.
1) Before using this product, make sure that the balloon inflates and deflates without fail.
2) Inflate the balloon slowly and carefully.
[Pressure of rapid injection may occasionally cause displacement or removal of the valve.]
3) Use a common, slip-type disposable syringe to inflate and deflate the balloon.
[A lock-type syringe cannot be inserted completely into the valve. If the taper does not fit, the valve may be damaged.]
4) When inflating/deflating the balloon, insert the tip of the syringe fully to the end of the valve and perform the operation.
[If the syringe tip is not sufficiently inserted into the valve, the inner valve in the valve may not work, making the balloon operation impossible.]
5) Only sterile distilled water should be used for balloon inflation.
[If physiological saline, contrast medium, etc. are used, the components may coagulate and the water may not be removed. If the balloon is inflated with air, it may deflate due to quick deaeration.]
6) Do not inject more than the specified volume of sterile distilled water into the balloon.
[Excessive injection may pressurize the balloon, and cause burst.]
7) When removing the syringe, be sure to hold the valve and rotate the syringe.
[In rare cases, displacement or coming off of the valve may be caused.]
[8] Do not suture the fixation plate to the skin.
[9] When removing the stopper or the multi-cap from the funnel, hold the stopper or multi-cap body firmly and remove it slowly and carefully.
[In particular, if the lid on the upper part of the multi-cap is pulled, it may be broken off.]
[10] When using the multi-cap, manage it correctly to prevent misconnection.
[The multi-cap has a shape that can be connected to syringes and infusion circuits used for vascular system.]
[11] When connecting a nutrition line, etc. to the end of the catheter, select a proper fitting. During use, check the connection for possible leakage or loosening as appropriate, and keep the product firmly connected.
[12] When connecting a connector, etc. to the funnel, insert the connector, etc. straight along the lumen of the funnel. Do not bend, twist, or pinch the funnel under this condition.
[The tip of the connector, etc. may damage the funnel lumen, leading to a crack or rupture of the funnel.]
[13] Take care not to apply any load such as pulling up of the balloon when attaching/detaching the nutrition line, etc.
[Balloon burst or catheter dislodgement may occur.]
[14] For administration of drugs, nutrients, etc., refer to the package inserts, etc. of these drugs, nutrients, etc.
[15] Before attaching the stopper or multi-cap, wipe off "wet" with nutrients, water, etc. at each part, and check the attachment status every time.
[If the attached part is wet or not sufficiently attached, the stopper or multi-cap may come off spontaneously and gastric contents may come out.]
[16] When the stopper or multi-cap is attached, check the attachment status every time.
[If the stopper or multi-cap is not sufficiently attached, the stopper or multi-cap may come off spontaneously and gastric contents may come out.]
[17] During insertion and placement of the catheter, make sure that the tip of the catheter has reached the correct position by several methods such as fluoroscopy, aspiration of gastric juice, confirmation of the depth mark position, or endoscopy.

[Precautions for Use]

< Important Precautions >

[1] Use a catheter suitable for the size of the fistula.
[If the catheter is too large, it may not be placed or the fistula may be damaged at the time of insertion]

[2] If a protective cap is attached to the connector tip of the nutrition line or the tip of the catheter tip syringe, be sure to remove it before connecting it to the funnel of this product.
[If the connector of the nutrition line or the catheter tip syringe is inserted into the funnel lumen without removing the protective cap, the cap may come off in the lumen and cannot be taken out, leading to possible clogging of the lumen.]

[3] Always flush with lukewarm water before and after administration of nutrients, etc.
[It is necessary to prevent clogging of the catheter due to accumulation of residual nutrients, etc.]

[4] Caution should be exercised when administering powder, etc. (especially drugs containing a binder, etc. as an additive) through a catheter because catheter clogging may occur.

[5] If resistance is felt during administration of nutrients, etc. or flushing with lukewarm water, etc., discontinue the operation.
[The catheter lumen may be occluded. If the operation is continued without eliminating the occlusion of the catheter lumen, the pressure in the catheter may increase excessively and the catheter may be damaged or ruptured.]

[6] When performing the operation to eliminate the clogging of the catheter, pay attention to the followings:
1. Use injectors, etc. with a large volume (30 mL or more is recommended).
[When using injectors with a volume less than 30 mL, the injection pressure increases and the possibility of catheter damage or rupture increases.]
2. Do not use a stylet or guidewire.
3. If the clogging of the catheter cannot be resolved by this operation, remove the catheter.

[7] During placement, manage the degree of balloon inflation by "lightly pulling the catheter", "using an endoscope", etc. If a burst or spontaneous leak is observed, immediately replace the catheter with a new one or take measures to prevent spontaneous removal of the catheter until it is replaced.
[If a balloon burst or spontaneous leak is left unattended and the catheter is removed spontaneously, the gastric fistula may be closed.]

[8] During placement, the position of the fixation plate should be managed using the depth mark as a guide.
[In rare cases, the catheter may be drawn into the intestinal tract and the fixation plate may be displaced. Peristaltic movement is likely to affect the area near the gastric antrum in particular.]

[9] Withdraw all the sterilized distilled water from the balloon approximately once a week and inject the specified volume of sterilized distilled water again.
[Decreased sterile distilled water may cause catheter dislodgement.]

[10] Do not hold this product firmly with a forceps, etc.
[The catheter may be damaged. In addition, the catheter may be cut, the lumen may be occluded, and the balloon may be damaged.]

[11] Keep the connection between this product and the nutrition line clean.
[Adhesion of dirt, oil, etc. to the connection site may cause detachment of the nutrition line and removal of the stopper or multi-cap during suspension of administration.]

[12] Metal is used inside the valve of this product. Therefore, when MRI (magnetic resonance imaging) is performed, attention should be paid to possible artifacts in image or local radiofrequency heating.

[13] Before using this product, make sure that there is no abnormality in each part.

[14] Do not insert forcibly. If insertion is difficult, discontinue the use and take appropriate measures.
[Forcible insertion of a gastrostomy catheter for replacement may damage the fistula. Fistula without placement due to accidental (self) removal, etc. narrows in a short time.]
[Forcible insertion of the exchange rod may cause damage (perforation, etc.). If the placed catheter lumen is occluded due to adhesion of nutrients, etc. or gastric contents, etc., an exchange rod may not be inserted.]

[15] Do not insert or remove forcibly, and operate with great care.
[The product may be damaged.]

[16] The condition of the placed product should be carefully monitored, and if any abnormalities are observed, the use of this product should be discontinued and appropriate measures should be taken.

[17] The patient's condition and the placement status of this product should be checked regularly.

[18] Do not modify this product.
[Addition of side holes may cause catheter breakage.]

[19] Do not use the product if the packaging is damaged or if any abnormality such as damage is found in the product.

[20] Use immediately after opening and dispose the product after use in a safe manner in each country.

[21] When a drug is injected into the body using this product, the appropriate drug should be selected under the responsibility of a physician. Refer to the package insert, etc. of the drug.

[22] During placement, the product should be carefully managed so that no untrained person can manipulate the product.

[23] Medical devices used in combination with this product should be handled according to the package insert and instruction manual of the product.

[24]  printed on the label indicates that the product should not be used if the package is damaged or opened.

[25]  printed on the label means that the contact part of the body fluid/drug solution does not contain phthalic acid.

[26] All serious incidents arising in connection with the device should be reported to the manufacturer and to the regulatory authorities of the member states where the user and/or patient resides.

< Defects >

Other Defects

[1] Balloon burst.
[Burst due to the following causes:]
- Damage caused by handling during insertion (damage caused by tweezers, forceps, scissors, scalpels, or other instruments).
- Infusion of excessive volume (more than the specified volume infused).
- Injection of wrong substances for balloon inflation (substances that are likely to cause coagulation of components such as physiological saline solution and contrast medium)
- Suddenly placing load on the product such as accidental (self) removal, etc.
- Other complex causes arising from the above events, etc.

[2] Catheter occlusion.
[The catheter lumen may be occluded by adhesion of drugs, nutrients, etc. or gastric contents, etc.]

[3] Unable to remove the catheter.
[If nutrients, etc. adhere to the catheter lumen due to inadequate flushing, etc., the tube may be deformed and the balloon lumen may be occluded, making it impossible to remove water. Also, if physiological saline or contrast medium is used for balloon inflation, the balloon lumen may be occluded due to coagulation of components, and it may become impossible to remove water.]

[4] Spontaneous fall-off of the stopper or multi-cap.
[If the stopper or multi-cap is loosened or wet in addition to the condition of high intragastric pressure due to the tendency to develop gas retention, sneezing, cough, etc., the stopper or multi-cap may spontaneously fall off and gastric contents may leak.]

[5] Catheter breakage
[Break due to the following causes]
- Damage caused by tweezers, forceps, scissors, scalpels, or other instruments.
- Suddenly placing load on the product such as accidental (self) removal, etc.
- Other complex causes arising from the above events, etc.

[6] Valve damage/leakage
[The valve may be damaged or have leakage due to local high-frequency heating.]

[7] Exchange rod break
[Break due to the following causes]
- Damage caused by tweezers, forceps, scissors, scalpels, or other instruments.
- Manipulation such as forcible insertion and removal.

<Adverse Events >

Serious Adverse Events

[1] Tissue compression necrosis due to excessive compression of the gastric wall and abdominal wall.

[2] Peritonitis associated with intraperitoneal leakage of nutrients, etc. due to wrong insertion of the catheter or fistula injury.

Other Adverse Events

[1] Use of the catheter may cause the following adverse events:
- Balloon burst, catheter dislodgement due to accidental (self) removal, etc. and associated fistula closure.
- Fistula injury due to insertion and removal and associated wound infection.
- Ulcer due to contact irritation of the catheter tip to the posterior gastric wall.
- Skin troubles around the fistula due to skin contact, gastric content leak and so on (granulation, redness, skin ulcer, pressure necrosis).
- Fistula dilatation associated with catheter manipulation.
- Gastrointestinal obstruction and associated difficulties in gastric juice emptying, gastric dilatation, vomiting, etc.
[Gastrointestinal obstruction may occur when the balloon part is drawn into the intestine due to gastric peristalsis.]
- Burns due to local high-frequency heating.

[2] Use of the exchange rod may cause the following adverse events:
- Damage (perforation, etc.)
- Bleeding.

< Use During Pregnancy, Delivery or Lactation and Pediatric Use >
Caution should be exercised when using x-rays in patients who are or may be pregnant.
[There is a concern that X-ray may affect fetuses.]

[STORAGE METHOD AND DURATION OF USE]
< Storage Method >
Store the product clean avoiding direct sunlight, high temperature and humidity, and ultraviolet rays such as germicidal lamps, and paying attention to wetting.

< Duration of Use >
This product is used for 29 days or less.
[Based on self-certification (our company data).]

< Expiration Date >
When the proper storage method has been maintained, refer to the expiration date on the individual package.
[Based on self-certification (our company data).]

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